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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,896	09/26/2001	Preeti Lal	PF-0527-2 DIV	2122

27904 7590 01/26/2004

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,896	LAL ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 11, 12, 31-45, 56 and 60-62* is/are pending in the application.

4a) Of the above claim(s) *1,12,44,45 and 56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,31,32,34,36-43 and 60-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's provisional election with traverse of Group VII (claims 11, 31, 32, 34, 36-43 and 60-62) in the Paper received October 31, 2003 is acknowledged. The traversal is on the ground(s) that the methods utilizing the elected product could and should be examined together per the commissioner's Notice in the Official Gazette of March 26, 1996 and in light of *In re Ochiai, In re Brouwer* and 35 U.,S.C 103(b). In addition Applicants argue that the restriction should not be set forth for Markush-type claims. These arguments and points of view have been carefully considered but found unpersuasive.

As indicated by the attached database sheet Applicants" SEQ ID NO: 1 and 2 share at most 20% sequence identity. There is not corresponding common core sequence. SEQ ID NO: 1 and 2 are different products. As to the question of examining the polypeptide, methods, as well as the elected antibody all three of these inventions are classified differently, necessitating different searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. Clearly different searches and issues are involved in the examination of each group. The provisions of *In re Ochiai, In re Brouwer* are clear as Applicants have noted in the Remarks received October 31, 2003. However, at this time in prosecution the product claims are not allowable, hence a rejoinder of the corresponding methods is moot. For reasons presented above and the restriction

requirement set forth in Paper mailed September 30, 2003 the said requirement is deemed to be proper and is adhered to.

The requirement is deemed proper and is therefore made FINAL.

2. Claims 1, 11, 12, 31-45, 56 and 60-62 are pending.

Claims 1, 12, 44, 45 and 56, drawn to non-elected inventions are withdrawn from examination.

Claims 2-10, 13-30, 33, 35, 46-55 and 57-59 have been cancelled.

Claims 60-62 have been added.

Claims 11, 31, 32, 34, 36-43 and 60-62 are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11, 31, 32, 34, 36-43 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 11 and 61 are broadly drawn to antibodies which bind the polypeptide comprising a naturally-occurring amino acid sequence having at least 90% sequence

identity to the sequence of SEQ. ID. NO: 1. Claims 31, 32, 34, 36-43, 60 and 62 are drawn to antibodies (i.e. monoclonal, humanized and polyclonal) and methods of making the said antibodies that specifically bind to the naturally occurring sequence having at least 90% sequence identity to SEQ ID NO: 1, as well as fragments of SEQ ID NO: 1. The specification while being enabling for antibodies that bind SEQ ID NO: 1, does not reasonably provide enablement for variants that have at least 90% sequence identity and antibodies that bind said variants. There is no guidance as to how to make these divergent sequences, which possess function in the absence of any information, on what functions the native protein possesses. Furthermore, there is no guidance as to how specific antibody binding would be to the 90% naturally occurring variants. Likewise, it would seem that specific function(s) would be required to make the said antibodies useful for the applications disclosed in the specification. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful. The true fact of the state of the art in peptide chemistry is expressed succinctly in the accompanying Lazar article (Molecular and Cellular Biology 8(3): 1247-1252, March 1988). This article presents data that substantiates the fact that the introduction of mutations in an amino acid sequence will yield products with different biological activity from the wild type protein. The specification does not teach what those are or how to determine what they are. Varied polypeptides would yield a vast collection of antibodies. The specification provides inadequate instruction to allow one skilled in the art to make and use the said naturally occurring polypeptides having at

least 90% sequence identity and their resulting antibodies with a reasonable expectation of success and without undue experimentation.

5. Claims 11, 31, 32, 34, 36-43 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11 and 61 are broadly drawn to antibodies which bind the polypeptide comprising a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ. ID. NO: 1. Claims 31, 32, 34, 36-43, 60 and 62 are drawn to antibodies (i.e. monoclonal, humanized and polyclonal) and methods of making the said antibodies that specifically bind to the naturally occurring sequence having at least 90% sequence identity to SEQ ID NO: 1, as well as an immunogenic fragment of the amino acid sequence of SEQ ID NO: 1. These claims are drawn to antibodies that are to bind SEQ ID NO: 1 and polypeptide fragments that possibly contain a small number of amino acid residues that is less than the 141 amino acids. Hence the claims are drawn to antibodies that bind amino acid residues that minimally contain only portions of SEQ ID NO: 1. Thus, the claims are drawn to a large genus of molecules. In the case of antibodies that allegedly bind small identified amino acid residues claimed with open language, the genus of polypeptides comprising only a partial sequence encompasses a variety of subgenera with widely varying attributes.

The specification discloses only the alleged structural features of one species of antibody, those that bind the polypeptide sequences of SEQ ID NO: 1. The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed. Applicant is referred to the interim guidelines concerning compliance with the written description requirement of 35 U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 11, 31, 32, 34, 36-43 and 60-62 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and a substantial asserted utility or a well established utility.

Applicants have asserted several utilities for the claimed antibodies (i.e. monoclonal, chimeric and fragments thereof), which bind specifically to the prostate growth-associated membrane protein set forth in SEQ ID NO: 1 and fragments thereof. The specification asserts the following utilities for the claimed antibodies: compositions for the diagnosis and prevention or treatment of solid and liquid cancers, as well as reproductive disorders, see the Specification page 4, lines 21-33; page 25, lines 24-32; page 33, lines 24-33. However, these asserted utilities are not credible, specific or substantial for the broadly claimed polypeptide. Other that the sequence identification

number, the specification provides no functional characterization of SEQ ID NO: 1, no specific tissue distribution of the polypeptide and no specific disease state in which these proteins affect. The broadly claimed antibodies specifically bind to polypeptides belong to a group, collectively referred to as prostate growth-associated membrane proteins (PGAMP). The PGAMP-1 protein identified as SEQ ID NO: 1 is reportedly shares chemical and structural similarity with the rat heat-stable antigen CD4 and is expressed in cancerous or hyperplastic prostate, breast and in brain and adrenal gland, see page 25, lines 14-18. Based on this analysis Applicants suggest "PGAMP-1 appears to play a role in neoplastic and reproductive disorders". Agonists and antagonists of PGAMP-1 polypeptides such as the claimed antibodies are suggested to prevent or treat the aforementioned disorders. However, there is no information that links expression of the SEQ ID NO: 1 polypeptide to **any specific** tissue or disorder. The listing of the varied cancers is diverse in pathology and the several organ systems are divergent in histology, see page 25, lines 24-30. Thus, the asserted utility of the claimed antibodies is not substantial, specific or credible.

Claims 11, 31, 32, 34, 36-43 and 60-62 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris,
22 January 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER